DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

HAND-DELIVERED

WARNING LETTER

FLA-97-29

July 22, 1997

Jay B. Weiss, President
Biogenetics Food Corporation
4475 Corporate Square Boulevard
Naples, Florida 33942

Dear Mr. Weiss:

During an inspection of your firm on June 20-21, 1996, FDA Investigator Alfred L. Chester determined that you market and distribute Cat's Claw and Nu-Green, which are being promoted to treat disease conditions.

We regard your promotional brochures as labeling which make therapeutic claims for these products. These claims cause these products to be drugs within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). These products are "new drugs" within the meaning of section 201(p) of the Act and, therefore, may not be marketed in the United States without approved new drug applications under section 505 of the Act.

Your promotional material describes "Cats Claw" as an herb used "in the treatment of arthritis, gastritis, certain cancers, and other known epidemic diseases". Your promotional material also offers "Cats Claw" for such serious conditions as "Chrone's [sic] disease, diverticulitis, recurring ulcers, and other intestinal conditions. The material further states that "Cats Claw" "combats inflammation and tumor growth."

In addition, the claims made for your product "Nu-Green" include "an immunization effect against many dietary carcinogens."

These claims cause the above referenced products to be misbranded within the meaning of section 502(a) because the labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established, and section 502(f)(1) because the labeling fails to bear adequate directions for use.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Dr., Suite #120, Orlando, Florida 32809, (407) 648-6823, ext. #264.

Sincerely,

Douglas D. Tolen
Director, Florida District